Background for Oxitec Ltd. Status and Meeting on October 16, 2017

Status of Realignment Effort: On October 4, 2017, FDA Guidance #236 clarifying jurisdiction between FDA and EPA on mosquito-related products published. The Oxitec mosquito has now realigned into EPA's regulatory responsibility.

Current Status of BPPD/Oxitec Interaction: Oxitec has not yet made a PRIA submission to OPP on its Friendly™ mosquito 513A. The table below describes the status of the major data/information development actions currently in play. OPP has met with Oxitec on several occasions over the past several months and communicated by letter detailed explanations of the various pieces of data/information necessary to support both experimental use permit and registration applications. Oxitec has indicated that it intends to submit protocol review PRIA submissions to determine U.S. equivalence of their efficacy data and then, if EPA determines the data is equivalent to U.S. data, submit an application for registration. If EPA determines that the data is not equivalent to U.S. data, Oxitec indicated that it would likely submit an experimental use permit (EUP).

Date	Action	Status
March 2017	BPPD describes data/information needed for a risk assessment.	Oxitec is still developing some of the data/information (e.g., protein data). They believe data will be available in November 2017.
May 2017	Oxitec and BPPD discuss data needed for an EUP and Oxitec submits summary	BPPD technical experts reviewed the materials and BPPD provided guidance in a June 2017 letter.
July 2017	Oxitec submitted data/information materials for EPA review for advice on the completeness of the materials as a registration application.	BPPD technical experts screened the materials and BPPD responded to Oxitec in September 2017. Protein data and U.S./U.S. equivalent efficacy data are outstanding and needed for registration.
September 2017	Oxitec asked whether BPPD would look at draft efficacy rationales to determine if Oxitec's foreign efficacy data is U.S. equivalent.	BPPD indicated it could review Oxitec's rationales and determine U.S. equivalence, provided they were submitted as protocol reviews under PRIA and Oxitec asked whether the study designs were adequate to satisfy U.S. efficacy needs. The PRIA category is B682 and has a 3-month timeframe.
October 11, 2017	Oxitec asks for feedback on protein data study design.	BPPD written response pending.

Our best guess on what they may ask for: Oxitec may ask for an expedited review time frame and may not submit separate protocol review requests. They will likely point out that the recent hurricanes may affect the mosquito population situation. We have heard from local experts that the first month post-hurricane is not necessarily a problem, but in subsequent months we may see an uptick in mosquito populations and mosquito borne disease.

The PRIA timeframe for a registration submission without an SAP is 13 months. BPPD has over 30 new active ingredients pending and expediting the Oxitec application will impact those PRIA dates. If Oxitec submits a complete package during the beginning of December, we could prioritize our screen of the submitted application and complete the screen by the middle of February.